IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:14-CV-120-BO

ADAM E. WARD,
Plaintiff,

v.

ORTHO-MCNEIL PHARMACEUTICAL, JANSSEN PHARMCEUTICAL, ALEX GORSKY, CEO, Johnson & Johnson, and JOHNSON AND JOHNSON COMPANY,
Defendants.

ORDER

This matter is before the Court on defendants' motion for summary judgment. [DE 72]. Also ripe are plaintiff's motions to appoint counsel [DE 63], appoint expert witness [DE 64], to amend complaint [DE 78], ands to strike an affidavit [DE 90], as well as defendant's motions to seal [DE 74] and to strike [DE 86]. For the following reasons, defendants' motions to seal and for summary judgment are granted, defendants' motion to strike is denied as moot, and plaintiff's motions are denied.

BACKGROUND

Plaintiff, an inmate in the custody of the North Carolina Department of Corrections, filed this *pro se* products liability in March 2014, alleging that his use of the pharmaceutical drug Risperdal and defendants' failure to provide adequate warnings caused him to develop gynecomastia and high prolactin levels. Specifically, plaintiff alleges that six months into the drug regimen, he began to experience extreme pain in his nipple area, developed hard lumps and swelling in his breast tissue, and suffered from discharge from his nipples. He was diagnosed with gynocomastia and treated with another medication. He asserts that defendants informed the

public that Risperdal was safe for consumer consumption, that he was injured as a result of consuming the drug, and that he is entitled to $12.4 million in damages for his physical and emotional injuries.

Risperdal, and its generic form, risperidone, are prescription antipsychotic medications used to treat patients with mental illness. Defendant Janssen, a wholly owned subsidiary of Johnson & Johnson, manufactures both drugs. According to his medical records, Mr. Ward was never prescribed Risperdal, but instead received the generic form of the drug, risperidone, which he took from May 2012 to May 2013. Patriot Pharmaceuticals, LLC (Patriot), which is not a named defendant to this suit, distributes the risperidone manufactured by Janssen. Other companies unrelated to defendants also distribute risperidone.

Per the requirements of the Federal Food and Drug Administration (FDA), Risperdal and risperidone are distributed with an accompanying warning label approved by the FDA. Patriot's labels include explicit warnings and precautions regarding hyperprolactinemia, prolactin elevations, and gynecomastia. Prison protocol and plaintiff's records indicate that Mr. Ward met with a treatment team to discuss, *inter alia*, the risks and possible side effects of the drug, including the warnings and precautions contained on the manufacturer's labels prior to receiving risperidone.

Mr. Ward first complained of pain and knots or cysts in his breasts and nipples in February 2008. In June 2011, a prison physician noted that he had an elevated prolactin level. In July 2011, he complained of gynecomastia and elevated prolactin levels, and was prescribed an MRI. In May 2012, he began taking risperidone. Four doses out of the seventeen entries on Mr. Ward's prescription report were risperidone received from Patriot. The remaining 13 doses were

obtained from two other companies, Major and Torrent, which are not parties to this suit. Plaintiff's prolactin level was 44.8 in June 2011, 14.2 in March 2013, and 41.7 in July 2013.

Shortly after plaintiff filed suit, the Court granted his motion to appoint counsel "to the extent that suitable counsel may be identified and is available and willing to accept the appointment *pro bono*." [DE 10 at 4.] It appears that Mr. Ward was never able to find a lawyer to take his case. [*See* DE 13]. He filed a second motion to appoint counsel, which was denied on June 24, 2014. [DE 19]. Plaintiff then moved the Court to appoint an expert witness to aid him in the presentation of his case. The Court denied plaintiff's motion on October 3, 2014, after finding that Rule 706 of the Federal Rules of Evidence does not allow the court to appoint an expert to aid an individual party, but only allows court-appointed experts to assist the court in understanding complex evidence. [DE 42 at 4]. Plaintiff designated no experts by the scheduling order's deadline of October 1, 2014. [DE 29]. Defendants timely filed their expert report on January 16, 2015, pursuant to an order extending the deadline for expert reports. [DE 52]. Plaintiff then filed a second motion seeking appointment of an expert [DE 64] and a third motion for appointment of counsel [DE 63]. Defendants filed their motion for summary judgment on April 1, 2015. [DE 72]. These motions, as well as plaintiff's motion to amend the complaint [DE 78], and two motions to strike [DE 86, 90] are pending before the Court.

I. Plaintiff's Motions

Plaintiff's motion to appoint counsel reiterates that he has been unable to find an attorney to handle his case and is unable to successfully prosecute the case on his own, therefore appointment of counsel is appropriate. There is no constitutional right to counsel in civil cases. *Cook v. Bounds*, 518 F.2d 779, 780 (4th Cir. 1975). Moreover, while a court "may request an attorney to represent any person unable to afford counsel" pursuant to 28 U.S.C. § 1915(e)(1),

this provision does not allow federal courts to order an attorney to represent a plaintiff in a civil case. *Mallard v. U.S. Dist. Court for the S. Dist. of Iowa*, 490 U.S. 296, 301 (1989) (holding § 1915(d), now amended and renumbered as § 1915(e)(1), does not authorize compulsory appointment of counsel). While it is unfortunate that plaintiff has been unable to find a lawyer able to represent him, the Court cannot force an attorney to accept appointment. *Matherly v. Johns*, 5:11-CT-3020-BR, 2012 WL 4447590, *3 (E.D.N.C. Sept. 25, 2012). Plaintiff's motion for appointment of counsel [DE 63] is denied.

Plaintiff again requests that the Court appoint him an expert witness pursuant to Rule 26(A)(2) of the Federal Rules of Civil Procedure and Rule 706 of the Federal Rules of Evidence. [DE 64]. Plaintiff asks the Court to appoint an expert witness to assist the Court in understanding of the effects of Risperdal. The Court does not find appointment of an expert witness necessary given its rulings, *infra*, on the summary judgment motion and, accordingly, denies the motion to appoint an expert witness.

Plaintiff also asks for leave to amend his complaint. [DE 78]. Leave to amend should be "freely give[n] . . . when justice so requires." Fed. R. Civ. P. 15(a)(2). A motion to amend, however, "may be denied where the motion has been unduly delayed and where allowing the amendment would unduly prejudice the non-movant." *Deasy v. Hill*, 833 F.2d 38, 40 (4th Cir. 1987). Motions to amend should be denied if the amendment seeks to add claims that would "substantially [alter] the nature of the lawsuit," as "[b]elated claims which change the character of the litigation are not favored." *Id.* at 42.

Plaintiff's motion to amend, filed on April 8, 2015, seeks to add two treatment providers to the lawsuit who allegedly reviewed his medical records and were negligent in allowing him to continue to take Risperdal. [DE 78]. The motion was filed over a year after the original

complaint and after the deadline for amending the pleadings, the close of discovery, and for the filing of dispositive motions. Though plaintiff argues that the delay resulted from the discovery of new information, the only information plaintiff could be referring to is that contained in his own medical history. He could have requested this information at any time, and indeed, was provided it during discovery on January 6, 2015. Allowing plaintiff to add claims that are only tangentially related to the original complaint and involve new defendants after the dispositive motions deadline would unduly prejudice defendants. *See, e.g., Equal Rights Ctr. v. Niles Bolton Assocs.*, 602 F.3d 597, 603 (4th Cir. 2010); *Acosta-Mestre v. Hilton Intern. Of Puerto Rico, Inc.*, 156 F.3d 49, 51 (1st Cir. 1998). Plaintiff's motion to amend is denied.

Last, plaintiff moves to strike the affidavit of Lacey Elberg. [DE 90]. The affidavit contains undisputed facts about defendants Janssen and Johnson & Johnson. Plaintiff provides no basis for his motion to strike, and the Court accordingly denies the motion.

II. Defendants' Motions

For good cause shown, the motion to seal defendants' memorandum in support of their motion for summary judgment [DE 74] is granted.

Defendants seek entry of summary judgment in their favor as to all claims. Summary judgment is proper only when, viewing the facts in the light most favorable to the non-moving party, there is no genuine issue of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986); *Cox v. Cnty. of Prince William*, 249 F.3d 295, 299 (4th Cir. 2001). An issue is "genuine" if a reasonable jury, based on the evidence, could find in favor of the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Cox*, 249 F.3d at 299. When addressing cross-motions for summary judgment, the court must ask "whether the evidence presents a sufficient disagreement

to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson*, 477 U.S. at 251.

In determining whether a genuine issue of material fact exists for trial, a trial court views the evidence and the inferences in the light most favorable to the nonmoving party. *Scott v. Harris*, 550 U.S. 372, 378 (2007). The party seeking summary judgment "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex.* 477 U.S. at 323. Once the moving party has met its burden, the non-moving party must then "set forth specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986).

Plaintiff argues that defendant's product caused him to develop gynecomastia and elevated prolactin levels. Under North Carolina law, claims involving defective products are evaluated under a negligence standard, which requires plaintiff to prove the essential elements of duty, breach, causation, and damages. *McCollum v. Grove Mfg. Co.*, 293 S.E.2d 632, 635 (N.C. Ct. App. 1982); *Lipscomb v. Orkin, Inc.*, No. 5:13-CV-111-FL, 2014 3510117 at *2 (E.D.N.C. July 14, 2014). Though proximate cause is often considered a fact issue for a jury, "[i]n cases involving complicated medical questions far removed from the ordinary experience and knowledge of laymen, only an expert can give competent opinion evidence as to the cause of the injury." *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F.Supp.2d 465, 478 (M.D.N.C. July 6, 2006) (internal quotation omitted); *see also Phillip v. GEO Grp., Inc.*, No. 5:09-CT-1335-FL, 2012 WL 5392120 at *6–7 (E.D.N.C. Nov. 5, 2012) *aff'd* 520 F. App'x 215 (4th Cir. 2013); *Day v. Brant*, 721 S.E.2d 238, 246 (N.C. Ct. App. 2012).

Plaintiff has offered no expert testimony demonstrating that risperidone caused his alleged injuries. He has not designated an expert witness. He has offered nothing more than his unsupported assertion that risperidone caused his injuries. This is insufficient to meet his burden at summary judgment. *See Phillip*, 2012 WL 5392120 at *7–8 (granting summary judgment where plaintiff's allegations of proximate cause were based on speculation through lay testimony); *Doe,* 440 F.Supp.2d at 478 (granting summary judgment for failure to meet burden of proof on causation where court excluded plaintiffs' proffered expert testimony); *Thacker v. City of Winston-Salem*, 482 S.E.2d 20, 203, *rev. denied*, 346 487 S.E.2d 571 (N.C. 1997) ("The record is devoid of any medical evidence to establish the necessary causal relationship without conjecture and remote possibility.").

Defendants also contend that plaintiff's claims that he was inadequately warned about the possible side effects of Risperdal and risperidone fail under the learned intermediary doctrine. North Carolina has adopted the learned intermediary doctrine, which provides a defendant who manufactures a product which is dispensed to patients by doctors, rather than directly, has only a duty to warn the doctor of the risks associated with the product's use. N.C. Gen. Stat. § 99B–5. Here, the labels for risperidone distributed by Patriot were FDA-approved and contained specific warnings and precautions regarding the possibility of hyperprolactinemia, prolactin elevations, and gynecomastia. Accordingly, plaintiff cannot maintain a failure to warn claim against defendants. *See, e.g., Foyle By & Through McMillian v. Lederle Laboraties*, 674 F.Supp. 530, 536 (E.D.N.C. Dec. 2, 1987); *Baraukas v. Danek Med., Inc.*, No 6:97-CV-613, 2000 WL 223508, *4 (M.D.N.C. Jan 13, 2000).

Accordingly, there is no genuine issue of material fact, and defendant's motion for summary judgment must be granted. Defendant's motion to strike plaintiff's affidavit [DE 86] is denied as moot.

CONCLUSION

For the foregoing reasons, defendants' motion for summary judgment [DE 72] and motion to seal [DE 74] are GRANTED. Defendant's motion to strike [DE 86] is DENIED AS MOOT. Plaintiff's motions [DE 63, 64, 78, 90] are DENIED. The Clerk is DIRECTED to enter judgment accordingly and to close the file.

SO ORDERED, this 30 day of June, 2015.

TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE